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<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/530,375	ORMEROD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konata M. George	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed December 8, 2004.
2. ☒ The allowed claim(s) is/are 24, 25, 30, 31, 37-51, 55-60 and 64-66 (renumbered 1-28).
3. ☒ The drawings filed on April 27, 2000 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

### **DETAILED ACTION**

Claims 24, 25, 30, 31, 37-51, 55-60 and 64-66 are pending in this application.

#### ***Action Summary***

1. Examiner acknowledges the cancellation of claims 28, 29, 32, 36, 52-54 and 61-63 via previous amendments. The above mentioned claims should not have been included in the previous office action.
2. The rejection of claims 24 and 25 under 25 U.S.C. 102(b) as being anticipated by Francoeur et al. is hereby withdrawn as applicant had amended the claims to remove azithromycin as an active agent.
3. The rejection of claims 24, 25, 37 and 38 under 25 U.S.C. 102(b) as being anticipated by Pittrof et al. is hereby withdrawn as applicant had amended the claims to remove FK 506 as an active agent.
4. The rejection of claims 24, 25, 30, 31 and 37-39 under 35 U.S.C. 103(a) over Pittrof et al. in view of San-Doz Ltd. is hereby withdrawn as applicant had amended the claims to remove FK 506 as an active agent.

#### ***Statement of Reasons for Allowance***

5. The following is an examiner's statement of reasons for allowance:  
  
The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious a topical formulation comprising the macrocyclic lactone antibiotic clarithromycin or an immunosuppressive macrolide chosen from sirolimus or

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SDZ ASM 981 and a permeation modulator. The closet prior art of Francoeur et al. and Pittrof et al. teaches a topical formulation comprising macrocyclic lactone antibiotic azithromycin and a permeation modulator and Pittrof et al. teaches a formulation comprising the immunosuppressive macrolide FK 506 and a permeation modulator. Both of these prior art references for not suggest or teach using clarithromycin, sirolimus or SDZ ASM 981 as an active agent together with a permeation modulator.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

6. Claims 24, 25, 30, 31, 37-51, 55-60 and 64-66 are allowed.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George



SHELLEY A. DODSON  
PRIMARY EXAMINER